PF-0420-2 DIV

What is claimed is:

- 1. An isolated polypeptide comprising an amino acid sequence selected from the group consisting of:
 - a) an amino acid sequence of SEQ ID NO:1,
- b) a naturally occurring amino acid sequence having at least 90% sequence identity to an amino acid sequence of SEQ ID NO:1,
 - c) a biologically active fragment of an amino acid sequence of SEQ ID NO:1, and
 - d) an immunogenic fragment of an amino acid sequence of SEQ ID NO:1.
 - 2. An isolated polypeptide of claim 1, having a sequence of SEQ ID NO:1.
 - 3. An isolated polynucleotide encoding a polypeptide of claim 1.
 - 4. An isolated polynucleotide encoding a polypeptide of claim 2.
 - 5. An isolated polynucleotide of claim 4, having a sequence of SEQ ID NO:2.
- 6. A recombinant polynucleotide comprising a promoter sequence operably linked to a polynucleotide of claim 3.
 - 7. A cell transformed with a recombinant polynucleotide of claim 6.
 - 8. A method for producing a polypeptide of claim 1, the method comprising:
 - a) culturing a cell under conditions suitable for expression of the polypeptide, wherein said cell is transformed with a recombinant polynucleotide, and said recombinant polynucleotide comprises a promoter sequence operably linked to a polynucleotide encoding the polypeptide of claim 1, and
 - b) recovering the polypeptide so expressed.

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- 9. A method of claim 8, wherein the polypeptide has the sequence of SEQ ID NO:1.
- 10. An isolated antibody which specifically binds to a polypeptide of claim 1.
- 11. An isolated polynucleotide comprising a polynucleotide sequence selected from the group consisting of:
 - a) a polynucleotide sequence of SEQ ID NO:2,
- b) a naturally occurring polynucleotide sequence having at least 90% sequence identity to a polynucleotide of SEQ ID NO:2,
 - c) a polynucleotide sequence complementary to a),
 - d) a polynucleotide sequence complementary to b), and
 - e) an RNA equivalent of a)-d).
- 12. An isolated polynucleotide of claim 11 comprising the polynucleotide sequence of SEQ ID NO:2.
- 13. An isolated polynucleotide comprising at least 60 contiguous nucleotides of a polynucleotide of claim 11.
- 14. A method for detecting a target polynucleotide in a sample, said target polynucleotide having a sequence of a polynucleotide of claim 11, the method comprising:
- a) hybridizing the sample with a probe comprising at least 20 contiguous nucleotides comprising a sequence complementary to said target polynucleotide in the sample, and which probe specifically hybridizes to said target polynucleotide, under conditions whereby a hybridization complex is formed between said probe and said target polynucleotide or fragments thereof, and
- b) detecting the presence or absence of said hybridization complex, and, optionally, if present, the amount thereof.
 - 15. A method of claim 14, wherein the probe comprises at least 60 contiguous

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nucleotides.

- 16. A method for detecting a target polynucleotide in a sample, said target polynucleotide having a sequence of a polynucleotide of claim 11, the method comprising:
- a) amplifying said target polynucleotide or fragment thereof using polymerase chain reaction amplification, and
- b) detecting the presence or absence of said amplified target polynucleotide or fragment thereof, and, optionally, if present, the amount thereof.
 - 17. A composition comprising a polypeptide of claim 1 and an acceptable excipient.
- 18. A composition of claim 17, wherein the polypeptide has the sequence of SEQ ID NO:1.
- 19. A method for treating a disease or condition associated with decreased expression of functional NTPPH, comprising administering to a patient in need of such treatment the composition of claim 17.
- 20. A method for screening a compound for effectiveness as an agonist of a polypeptide of claim 1, the method comprising:
 - a) exposing a sample comprising a polypeptide of claim 1 to a compound, and
 - b) detecting agonist activity in the sample.
- 21. A composition comprising an agonist compound identified by a method of claim 20 and an acceptable excipient.
- 22. A method for treating a disease or condition associated with decreased expression of functional NTPPH, comprising administering to a patient in need of such treatment a composition of claim 21.

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- 23. A method for screening a compound for effectiveness as an antagonist of a polypeptide of claim 1, the method comprising:
 - a) exposing a sample comprising a polypeptide of claim 1 to a compound, and
 - b) detecting antagonist activity in the sample.
- 24. A composition comprising an antagonist compound identified by a method of claim 23 and an acceptable excipient.
- 25. A method for treating a disease or condition associated with overexpression of functional NTPPH, comprising administering to a patient in need of such treatment a composition of claim 24.
- 26. A method of screening for a compound that specifically binds to the polypeptide of claim 1, said method comprising the steps of:
- a) combining the polypeptide of claim 1 with at least one test compound under suitable conditions, and
- b) detecting binding of the polypeptide of claim 1 to the test compound, thereby identifying a compound that specifically binds to the polypeptide of claim 1.
- 27. A method for screening a compound for effectiveness in altering expression of a target polynucleotide, wherein said target polynucleotide comprises a sequence of claim 5, the method comprising:
- a) exposing a sample comprising the target polynucleotide to a compound, under conditions suitable for the expression of the target polynucleotide,
 - b) detecting altered expression of the target polynucleotide, and
- c) comparing the expression of the target polynucleotide in the presence of varying amounts of the compound and in the absence of the compound.
 - 28. A method for assessing toxicity of a test compound, said method comprising:
 - a) treating a biological sample containing nucleic acids with the test compound;

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- b) hybridizing the nucleic acids of the treated biological sample with a probe comprising at least 20 contiguous nucleotides of a polynucleotide of claim 11 under conditions whereby a specific hybridization complex is formed between said probe and a target polynucleotide in the biological sample, said target polynucleotide comprising a polynucleotide sequence of a polynucleotide of claim 11 or fragment thereof;
 - c) quantifying the amount of hybridization complex; and
- d) comparing the amount of hybridization complex in the treated biological sample with the amount of hybridization complex in an untreated biological sample, wherein a difference in the amount of hybridization complex in the treated biological sample is indicative of toxicity of the test compound.
- 29. A diagnostic test for a condition or disease associated with the expression of NTPPH in a biological sample comprising the steps of:
- a) combining the biological sample with an antibody of claim 10, under conditions suitable for the antibody to bind the polypeptide and form an antibody: polypeptide complex; and
- b) detecting the complex, wherein the presence of the complex correlates with the presence of the polypeptide in the biological sample.
 - 30. The antibody of claim 10, wherein the antibody is:
 - (a) a chimeric antibody;
 - (b) a single chain antibody;
 - (c) a Fab fragment;
 - (d) a F(ab')₂ fragment; or
 - (e) a humanized antibody.
 - 31. A composition comprising an antibody of claim 10 and an acceptable excipient.
- 32. A method of diagnosing a condition or disease associated with the expression of NTPPH in a subject, comprising administering to said subject an effective amount of the

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composition of claim 31.

- 33. A composition of claim 31, wherein the antibody is labeled.
- 34. A method of diagnosing a condition or disease associated with the expression of NTPPH in a subject, comprising administering to said subject an effective amount of the composition of claim 33.
- 35. A method of preparing a polyclonal antibody with the specificity of the antibody of claim 10 comprising:
- a) immunizing an animal with a polypeptide of SEQ ID NO:1 or an immunogenic fragment thereof under conditions to elicit an antibody response;
 - b) isolating antibodies from said animal; and
- c) screening the isolated antibodies with the polypeptide thereby identifying a polyclonal antibody which binds specifically to a polypeptide of SEQ ID NO:1.
 - 36. An antibody produced by a method of claim 35.
 - 37. A composition comprising the antibody of claim 36 and a suitable carrier.
- 38. A method of making a monoclonal antibody with the specificity of the antibody of claim 10 comprising:
- a) immunizing an animal with a polypeptide of SEQ ID NO:1 or an immunogenic fragment thereof under conditions to elicit an antibody response;
 - b) isolating antibody producing cells from the animal;
- c) fusing the antibody producing cells with immortalized cells to form monoclonal antibody-producing hybridoma cells;
 - d) culturing the hybridoma cells; and
- e) isolating from the culture monoclonal antibody which binds specifically to a polypeptide of SEQ ID NO:1.

- 39. A monoclonal antibody produced by a method of claim 38.
- 40. A composition comprising the antibody of claim 39 and a suitable carrier.
- 41. The antibody of claim 10, wherein the antibody is produced by screening a Fab expression library.
- 42. The antibody of claim 10, wherein the antibody is produced by screening a recombinant immunoglobulin library.
- 43. A method for detecting a polypeptide of SEQ ID NO:1 in a sample comprising the steps of:
- a) incubating the antibody of claim 10 with a sample under conditions to allow specific binding of the antibody and the polypeptide; and
- b) detecting specific binding, wherein specific binding indicates the presence of a polypeptide of SEQ ID NO:1 in the sample.
- 44. A method of purifying a polypeptide of SEQ ID NO:1 from a sample, the method comprising:
- a) incubating the antibody of claim 10 with a sample under conditions to allow specific binding of the antibody and the polypeptide; and
- b) separating the antibody from the sample and obtaining purified polypeptide of SEQ ID NO:1.